METHOD AND ARRANGEMENT FOR DETECTING THE CONDITION OF A BLOOD VESSEL ACCESS

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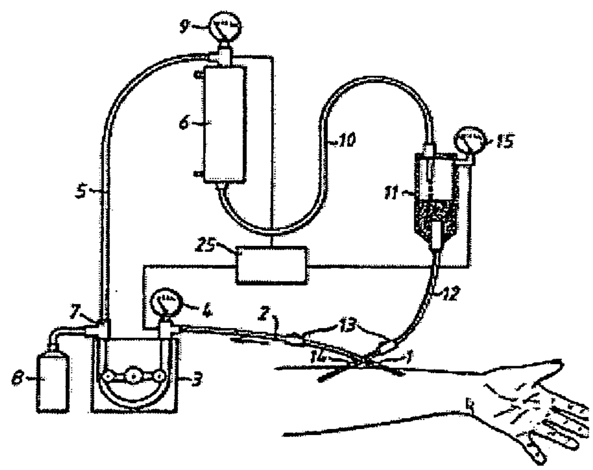
Abstract of **WO9710013**

The heart produces a pressure wave which passes via the blood vessel access (1, 14) and is sensed by a pressure detector (4, 15) on the other side of the blood vessel access. The signal obtained comprises interference signals which are separated via a processing arrangement (25) in order to obtain the pulse signal. Absence of the pulse signal indicates a malfunction in the blood vessel access. A blood pump in an extracorporeal blood circuit can be used as a pressure wave generator.



METHOD AND ARRANGEMENT FOR DETECTING THE CONDITION OF A BLOOD VESSEL ACCESS

Description of **WO9710013**

TITLE
METHOD AND ARRANGEMENT FOR DETECTING THE CONDITION OF A BLOOD VESSEL ACCESS
FIELD OF THE INVENTION
The invention relates to a method for detecting the condition of a blood vessel access with extracorporeal blood treatments such as hemodialysis, hemodiafiltration, hemofiltration, plasmapheresis or similar treatments. The invention also relates to an arrangement for carrying out the method.

STATE OF THE ART
A blood vessel access occurs by introduction of a needle or a catheter into a blood vein.

With hemodialysis, the blood vessel access is constituted by one or more needles or catheters, through which blood is taken out to an extracorporeal blood circuit where the treatment occurs. With hemodialysis the blood normally passes through the extracorporeal blood circuit at relatively high speed in the order of up to 500ml/min. Blood is normally taken out via an arterial needle and reintroduced into the body via a vein needle.Hemodialysis using a single needle (single needle dialysis) or catheters also exists.

If the blood vessel access, such as the arterial needle and/or the vein needle, is not placed correctly, malfunctions occur.

If the arterial needle is positioned too close to the walls of the blood vessel, it can be difficult to achieve sufficient blood flow with the available pump capacity. If the arterial needle is placed outside the blood vessel, the needle will become blocked by the tissues and no blood flow will be obtained at all. If the arterial needle is outside the body, air will be sucked into the circuit. These conditions are relatively simple to detect in the extracorporeal blood circuit.

If however the vein needle is unintentionally loosened, a lifethreatening situation can rapidly arise since, due to this, the patient can lose a large amount of blood in a short time.

With hemodialysis, the dialysis machine is provided with a plurality of detectors which detect dangerous situations and activate clamp devices which stop the extracorporeal blood flow when dangerous conditions arise.

Normally the dialysis machine is provided with an artery pressure sensor which measures the pressure in the extracorporeal blood circuit before the circulation pump. An underpressure of between -20 mm Hg and -80 mm Hg is normally present even though levels as low as -200 mm Hg can be produced with large blood flows. If the pressure approaches atmospheric pressure, this indicates that air is being sucked into the system, whilst an underpressure which is much too low (below -200 mm Hg) indicates that the arterial needle can be blocked or not properly inserted into the blood vessel or the fistula. Other causes can be that the arterial tube is kinked or that the fistula has collapsed due to an incorrect arm position.

The dialysis machine is further provided with a vein pressure sensor after the dialyser but before the vein needle, normally in connection with a vein drip chamber where the vein pressure is normally between +50 and +150 mm Hg. The pressure can vary depending on the size of the vein needle, variations in the blood flow and the composition of the blood, blocking of the vein needle or the vein blood tubes, or a separate vein blood filter which is often present in the drip chamber. Additional causes can be that the vein needle is unsuitably placed or that the vein tube is kinked. Further causes are changes in the height location of the fistula, for instance if the patient is sitting or lying.

If the vein needle comes out of the fistula, a reduction of pressure at the vein sensor will occur, which can be detected.

This detection is however rather uncertain. If the tube is moved upwardly through a holder somewhere and the end gets stuck higher up than the arm, it can happen that the pressure in the vein sensor is not reduced at all, or is only reduced insignificantly so that a set alarm level is not underpassed. Additionally, it may happen that the vein needle comes out when the patient turns, there being at the same time a risk that the patient will lie on the tube so that it is completely or partially blocked, or that the tube will kink.

There is therefore a desire to have a separate detection of whether the needle, used in connection with hemodialysis or another extracorporeal blood treatment, is still adequately in position at the blood access site, and in this respect in particular the vein needle.

This problem has previously been solved by providing the vein needle and/or the arterial needle with some form of sensor which detects if the needles move from a predetermined position. One example is providing the needles with magnets and arranging the sensors on the arm which senses whether said magnets are close to the sensors. Another way would be to provide the arm with a conductivity detector which gives a signal if blood leaks out.

The disadvantage with such detectors is that they have to be attached to the patient and simultaneously be electrically connected to the dialysis machine in order to stop the blood pump and disengage the extracorporeal circuit during a malfunction condition.

With catheters for blood vessel accesses, clogging may occur or the catheter's opening may be located too close to the blood vessel s wall and get stuck due to suction.

EP-A2-121 931 discloses an apparatus and method for use in a parenteral administration system for detecting fault conditions.

In one embodiment the fault detection means high pass filters the pressure signals to pass only the signal components attributable to patient's heartbeats. An alarm signal is produced whenever a dropout in the heartbeat pulses is detected.

EP-A2-332 330 discloses in infusion system for infusing a fluid into a patient comprising an infusion device for delivering the fluid in both a normal delivery pattern and a test puls and a conduit for conducting the fluid from the infusion device to the patient. The test pulse creates a pressure wave response in the conduit. Abnormal diffusion can be detected by determining the area between a base line and at least a portion of a pressure versus time curve representing the pressure wave respons.

SUMMARY OF THE INVENTION

The object of the present invention is to provide a method and an apparatus for detecting the condition of a blood vessel access, which detection is safe, reliable and simple.

The present invention is based on the integrity of the blood vessel access being able to be detected by transmission of a pressure wave from one side of the blood vessel access to the other side. There is thus a pressure wave generator on one side of the blood vessel access and a detection device on the other side.

In a preferred embodiment, the patient's heart is used as the pressure wave generator whilst a pressure sensor is arranged on the other side of the blood vessel access, i.e. in the tube which leads from the catheter or the needle and further out of the patient. A separate pressure wave generator can of course also be arranged on the patient, for example in the form of an armband provided with a pressure wave generator which presses against the surface of the skin, for instance at the wrist.

A suitable frequency for the pressure wave generator is circa 0,2
Hz to circa 20 Hz. By "pressure wave" is meant the type of pressure wave which is produced by a pump or the heart and can comprise sound, in particular infrasound. The present invention uses the transmission of a pressure wave or infrasound through a fluid, such as blood, and the vessels or tubes and the apparatus which is connected thereto, which also includes passage through air.

In connection with an extracorporeal circuit with an arterial needle and a vein needle, an existing blood pump in the extracorporeal blood circuit can be used as the pressure wave generator, said blood pump generating powerful pressure waves.

With hemodialysis, it is common to use a peristaltic pump which produces similar pressure waves. This pressure wave passes from the blood pump through the arterial needle to the blood vessel as well as via the blood vessel to the vein needle and from there to a pressure sensor arranged in connection with the vein needle.

Through signal analysis at the pressure sensor it can be established whether the path for the pressure wave through the blood vessel access disappears or changes radically, which is an indication of a modified condition of the blood vessel access.

With the above-mentioned extracorporeal blood circuit, the heart can also be used as the pressure wave generator and detect the pressure wave after the blood vessel access in order to detect the integrity or the condition of these needles. In this case it is necessary to filter the signal which is obtained from the pressure sensor in order to remove pressure waves from other sources than the heart, such as said blood pump.

Different methods for determining whether an alarm signal should be produced or not are also described.

BRIEF DESCRIPTION OF THE DRAWINGS
The invention will now be described in more detail with reference to the accompanying drawings.

Fig. 1 is a side view showing an arm provided with a fistula intended for dialysis.

Fig. 2 is a schematic view which shows the extracorporeal blood circuit in a conventional dialysis machine.

Fig. 3 is a diagram showing the pressure signal from an arterial sensor.

Fig. 4 is a diagram showing the pressure signal in Fig. 3 resolved in the frequency plane.

Fig. 5 is a diagram corresponding to Fig. 4 after filtering the signal.

Fig. 6 is a diagram which shows the pressure signal from the arterial sensor after filtering.

Fig. 7 is a schematic view showing the extracorporeal blood circuit with single needle dialysis.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS
Fig. 1 shows the left arm of a patient provided with a fistula suitable for hemodialysis. A fistula has shown itself to be the most effective, durable, permanent blood vessel access for extracorporeal blood treatment.

A fistula is created by surgical intervention, whereby a connection is formed between an artery and a proximate vein, for example in the lower arm. The fistula is formed either by an opening being formed from the sidewall of the artery to the sidewall of the vein as shown in Fig. 1, or by an opening in the sidewall of the artery being connected with the end of a vein. By means of the fistula, the bloodflow in the artery is short-circuited to the vein, which leads to an arterializing of the vein and an increased bloodflow in the vein which allows taking out of bloodflows up to 500 ml/minute or more.

As is clear from Fig. 1, the arterial needle which leads to the extracorporeal circuit is always placed in the part of the arterialized vein which faces the hand, but at least three centimetres downstream of the connection between the artery and the vein. The arterial needle can either point towards the hand as shown in Fig. 1 or in the other direction. The vein needle is to be inserted directed towards the heart, approximately five centimetres from the arterial needle.

The expression "fistula" will be used below for the part of the arterialized vein where the needles are inserted.

Other types of blood vessel accesses can be used such as a Scribner-shunt or one or more catheters.

Fig. 2 shows an extracorporeal circuit of the type which is used in a dialysis machine. The circuit comprises an arterial needle 1 and an arterial tube 2 which connects the arterial needle 1 to a blood pump 3 which is normally of peristaltic type such as indicated in Fig. 2. At the inlet of the pump there is an arterial sensor 4 which measures the pressure immediately before the pump in the arterial tube 2. The blood pump 3 leads the blood further, via a tube 5, to a dialyser 6. The tube 5 can comprise an inlet 7 for heparin connected to a heparin pump 8. Many dialysis machines are additionally provided with a pressure sensor 9 which measures the pressure between the blood pump 3 and the dialyser 6, the so-called system pressure. The blood is lead via a tube 10 from the dialyser 6 to a vein drip chamber 11 and from there back to the patient via a vein tube 12 and a vein needle 14.The vein tube 12 is provided with a clamp device 13 which stops the blood flow upon a malfunction condition. The vein drip chamber 11 is provided

with a vein sensor 15 which measures the pressure in the vein drip chamber. The arterial tube 2 can also be provided with a clamp device similar to the clamp device 13. Both the arterial needle 1 and the vein needle 14 are inserted into said fistula.

When the blood passes the arterial needle 1, which has a small a cross-sectional area as possible so as not to damage the fistula, the pressure sinks to between circa -20 to -80 mm Hg, which is measured by the arterial sensor 4. The pressure rises in the pump 3, said pressure being measured by the system sensor 9. In the dialyser 6, the pressure falls due to the flow resistance therein and the pressure after the dialyser is measured with the vein sensor 15, normally in the vein drip chamber. The pressure in the vein drip chamber is normally between +50 to +150 mm Hg. Finally the blood is released to the fistula via the vein needle 14, whereby a pressure drop occurs in the needle due to the flow through its small cross-section.

The aforementioned pressure conditions vary considerably from patient to patient and can even vary for one and the same patient between different treatment sessions. It is therefore difficult to set up limit values for the pressure sensors which indicate different error conditions. It is particularly difficult to indicate whether the vein needle 14 is coming out of the fistula, particularly if the vein tube 12 is hanging over a position so that the vein needle is moved upwardly a long way when it comes out.

In many dialysis machines one or more of said pressure detectors are not present. Normally however there will be at least one vein pressure sensor.

Fig. 3 shows a pressure curve which is obtained from the arterial sensor 4 in Fig. 2. This pressure curve corresponds to the pressure curve of the blood pump 3 on its suction side. The pressure pulses emanate from the time instances when one pressure roller takes over from the other pressure roller, i.e. showing the pump stroke.

The pressure curve in Fig. 3 corresponds to the bloodpump's suction stroke but also has a superimposed pulse signal obtained from the pulse in the fistula. This pulse signal is however very insignificant and cannot be observed with the naked eye in Fig.

3.

In Fig. 4, the pressure curve in Fig. 3 has been resolved in the frequency plane (Fourier-transformation). It can be seen that the signal consists of a base frequency, fo, at about 52 strokes per minute, as well as a large number of harmonics, of which only three can be identified in Fig. 4.

By eliminating the frequency fo and its harmonics, the effect of the bloodpump's pressure pulses on the pressure in the arterial sensor 4 can be eliminated. Such elimination can be done with the aid of notch filters.

If the frequency and phase of the interference are known, notchequivalent filters can advantageously be used. One example is the generation of sinus signals at the known frequency together with its harmonics and the subtraction of these from the signal at suitable phase. With an adaptive filter, the amplitude and the phase of the generated signals can be determined. This filter technique is known. The calculations and the subtraction suitably occur in a signal processor. The signal processor and its analogue/digital converter must however have high resolution since the pulse signal is very weak.

Fig. 5 shows the signal in Fig. 3 in the frequency plane after subtraction of the interference due to the bloodpump's pressure waves, i.e. subtraction of the base frequency fo and its harmonics. From Fig. 5 it can be seen that a half base frequency, i.e. 0.5 fo, is also represented in the frequency plane together with the corresponding harmonics 1.5 fo, 2.5 fo, 3.5 fo etc. (fo, 2fo, 3fo etc. have already been eliminated). This half base frequency is due to the fact that the blood pump used is of peristaltic type with two rollers which act on the tube segment in the blood pump. The rollers are probably not entirely symmetrical, which gives rise to the half base frequency (0.5 fo).

Half the base frequency is also the same as the motor's rotational speed. This rotational speed is known since it is generated by the dialysis machine. The motor which drives the blood pump can be constituted by a stepping motor which is driven at predetermined frequency. By using this known frequency signal or the known rotational speed of the blood pump, the frequency fo can be determined very accurately which results in an accurate removal of these frequency components.

Fig. 6 shows the signal which is obtained after the abovementioned adaptive filtering and elimination of the pump frequency and its harmonics. Moreover the pulse signal has passed a band-pass filter which lets through the frequencies 30-180 strokes/minute (0,5-3 Hz). As is clear from Fig. 6, the amplitude of the pulse signal is dependent on many factors, such as damping in tubes etc. Other factors can be a change

in height position of the arm or that the needle has temporarily come closer to the wall of the fistula.

Even though Figs. 3 - 6 relate to the pressure conditions of the arterial needle, the conditions are similar with a vein needle.

An indication that the needle has fallen out is that the amplitude of the pulse signal sinks to zero. In practice, an alarm signal can be emitted if the amplitude sinks below 20% of an earlier determined normal amplitude. This normal amplitude can be determined during the first stage of the treatment when the dialyser is being observed by a nurse, for example during the first half hour of the treatment.

The pulse signal can disappear temporarily for other reasons than the needle having fallen out, such as the patient moving. The adaptive signal processing then re-adjusts the settings to the new situation, after which the pulse signal can be recovered and separated. Such an adaptive adjustment to normal but changed situations takes a certain amount of time. It is therefore suitable if the emitting of an alarm signal is delayed by a short space of time of the order of a number seconds.

Another way of determining when an alarm signal is to be emitted is to determine the relationship between the amplitude of the pulse signals from the vein sensor 15 and the pulse signal from the arterial sensor 4. Due to the different damping in, for instance, the blood tube 2 and the blood tube 12 respectively, as well as the vein drip chamber 11, the amplitude from these sensors is different, whereby the vein sensor 15 generally has a lower amplitude.

If the pulse signal from the vein sensor 15 disappears more or less completely at the same time as the pulse signal from the arterial sensor 4 is still present and substantially unchanged, this is a certain sign of a problem with the vein needle 14; either that it has come too close to the blood vessel wall or fallen out completely. According to the present invention it is proposed that the alarm signal is emitted when the relationship between the amplitudes for the pulse signals from the vein sensor 15 and the arterial sensor 4 respectively are changed substantially, such as the relationship between the amplitudes sinking below a limit value which is 50% of the original value.

If it is desired to obtain greater accuracy for the detection, said limit value can instead be set at 30%. If there is a patient who has weak blood vessels, whereby it can easily happen that the vein needle 14 comes too close to the blood vessel wall, or if problems arise in another way which can be acceptable and would not lead to an alarm, the limit value should be set even lower, such as at 20%.

If the amplitude of the pulse signal from the arterial sensor 4 reduces greatly, this is probably an indication of a problem with the arterial needle 1 which can also give rise to an alarm signal.

From Fig. 5 it can be seen that if the frequency of the pulse lies close to the half base frequency (0.5 fo) of the blood pump or multiples thereof, difficulties will occur in separating the pulse signal from the blood pump signal. In particular there will be difficulties in such a separation if the difference between the pulse and any of the bloodpump's frequencies is less than circa 5-10%. In accordance with the invention it is suggested that the blood pump is adapted so that the pulse always lies at at least circa 10% from any of the bloodpump's frequency components. This can be done by making the blood pump increase or decrease its speed by aboutf108 when the pulse detection system according to the invention senses that there is a risk of collision. Such a change of the bloodpump's speed will hardly be noticed by the patient. In order to reduce the risk of exceeding any maximum possible bloodflow speed, said regulation can be -15% to 5% or -20% to0% or something similar.

The frequency of the pulse signal can be used for other purposes such as are known per se. Thus, a great rise in the pulse implies that there is a risk for shock, etc.

Since the pressure pulses of the blood pump 3 are strong, these pressure pulses can be transmitted to the vein sensor 15 via a path which comprises the tube 2, the arterial needle 1, the fistula, the vein needle 14 and the tube 12 to the vein sensor 15. If the arterial needle 1 and/or the vein needle 14 comes out, said path for the pressure pulses will be broken and thus will cease. This characteristic can be used in order to detect the integrity of both the arterial needle and the vein needle simultaneously.

Fig. 2 shows a pressure sensor 9 for the system pressure. The pressure wave from the blood pump 3 passes via the system sensor 9 and the dialyser 6 to the vein sensor 15. In this way there is both a time delay from the system sensor 9 to the vein sensor 15 and a damping.

The system sensor 9 is positioned so that the pulse signal is very small or completely absent. By comparing the signals from the arterial sensor 4, the vein sensor 15 and the system sensor 9, suitable conditions for emitting an alarm signal can be determined.

Fig. 7 shows a schematic circuit similar to Fig. 2 for singleneedle dialysis, whereby the same reference numerals have been used for the same components as in Fig. 2. The difference compared to two-needle dialysis is merely that one needle is used. Furthermore expansion vessels 21 and 22 are required and often a second pump 23. The system pressure sensor 9 is often placed after the dialyser 6. Apart from this, the function is basically the same as described above, in as far as concerns the present invention.

Frequencies between circa 0.2-20 Hz have been quoted above. The reason for the use of these frequencies is that they are in the infrasound range and do not give rise to audible sound. It is useful to use frequencies of about 1 Hz since many patients find this frequency calming, presumably due to the fact that it is close to the frequency of the heart. Normally however, it is preferable to use frequencies for the blood pump which differ from the heart frequency if the pulse is to be used as an indication, for example 1.5 Hz and upwards or below circa 0.8
Hz..

An ultrasound generator can also be used as the pressure wave generator, it being coupled to the blood vessel via an arm band as described above, or to the extracorporeal blood circuit for transmission via the blood vessel access as described above. A suitable ultrasound frequency ought to lie at just above 20 kHz, for instance 20-40 kHz. In principle it is possible to use frequencies within the range 20-20 000 Hz, but this is not preferred since it is apparently experienced to be disturbing by the patients and personnel.

The principles of the invention can also be applied for detecting the condition of another component in the extracorporeal circuit, such as the dialyser, by letting a pressure wave pass through the component and detecting the changed condition with a pressure sensor.

The invention can also be used for other applications than those described in detail above, such as those mentioned in the introduction, like hemofiltration etc. The various electronic means for obtaining the desired function have not been described above although a skilled man will realise various possibilities and can practice the invention without a detailed account of any embodiments. The invention is only limited by the appended claims.

METHOD AND ARRANGEMENT FOR DETECTING THE CONDITION OF A BLOOD VESSEL ACCESS

Claims of **WO9710013**

CLAIMS

1. Method for detecting the condition of a blood vessel access, comprising an extracorporeal blood flow circuit which is coupled to a blood vessel of a patient via said blood vessel access, characterized by generating a pressure wave by means of a pressure wave generator arranged on one side of the blood vessel access and sensing the pressure wave by means of a pressure sensor on the other side of the blood vessel access.

2. Method according to claim 1, characterized in that the pressure wave generator produces pressure waves with a frequency of between circa 0.2 Hz and 20 Hz.

3. Method according to claim 1 or 2, characterized in that the pressure wave generator is constituted by the patient's heart, and in that the pressure sensor is arranged in the extracorporeal blood flow circuit.

4. Method according to claim 1 or 2, in which the extracorporeal blood flow circuit comprises a pump, such as a blood pump, characterized in that the pressure wave generator is constituted by said pump, whereby the pressure wave passes to the pressure sensor via a path through the blood vessel access, and in that the absence of this path is detected.

5. Method according to claim 3, wherein the extracorporeal blood flow circuit comprises a pump, such as a blood pump, characterized in that the signal of the pressure sensor is processed by subtraction of a pressure signal corresponding to a pressure wave obtained from the pump in order to obtain a pulse signal corresponding to the patient's heartbeat.

6. Method according to any one of the claims 1, 2 or 4, characterized in that said pressure wave passes a component in the extracorporeal blood flow circuit, and in that the condition of this component is sensed.

7. Arrangement for detecting the condition of a blood vessel access, comprising an extracorporeal blood flow circuit which is connected to a blood vessel of a patient via said blood vessel access, characterized by a pressure wave generator (3) for generating a pressure wave arranged on one side of the blood vessel access, and a pressure sensor (4, 15) for sensing the pressure wave arranged on the other side of the blood vessel access.

8. Arrangement according to claim 7, characterized in that the pressure wave generator (3) produces pressure waves with a frequency of between circa 0.2 Hz and 20 Hz.

9. Arrangement according to claim 7 or claim 8, characterized in that the pressure wave generator is constituted by the patient's heart, and in that the pressure sensor (4, 15) is arranged in the extracorporeal blood flow circuit.

10. Arrangement according to claim 7 or 8, wherein the extracorporeal blood flow circuit comprises a pump, such as a blood pump (3), characterized in that the pressure wave generator is constituted by said pump (3), whereby the pressure wave passes to the pressure sensor (15) via a path through the blood vessel access, and by an arrangement (25) for detecting the absence of said path.

11. Arrangement according to claim 9, wherein the extracorporeal blood flow circuit comprises a pump, such as a blood pump (3), characterized by a processing arrangement (25) for processing the pressure generator's signal by subtraction of a pressure signal corresponding to a pressure wave obtained from the pump in order to obtain a pulse signal corresponding to the patient's heartbeat.

Fig.1

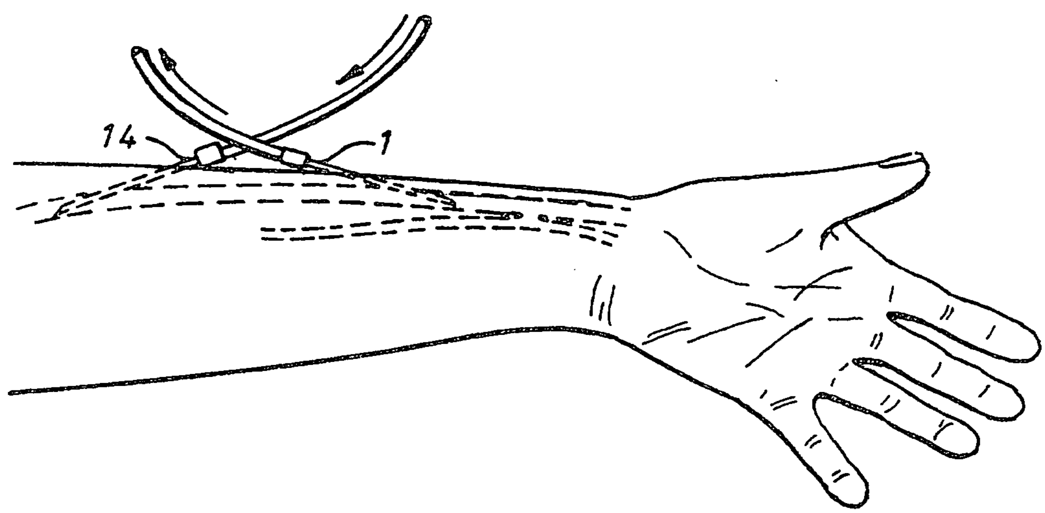


Fig.2

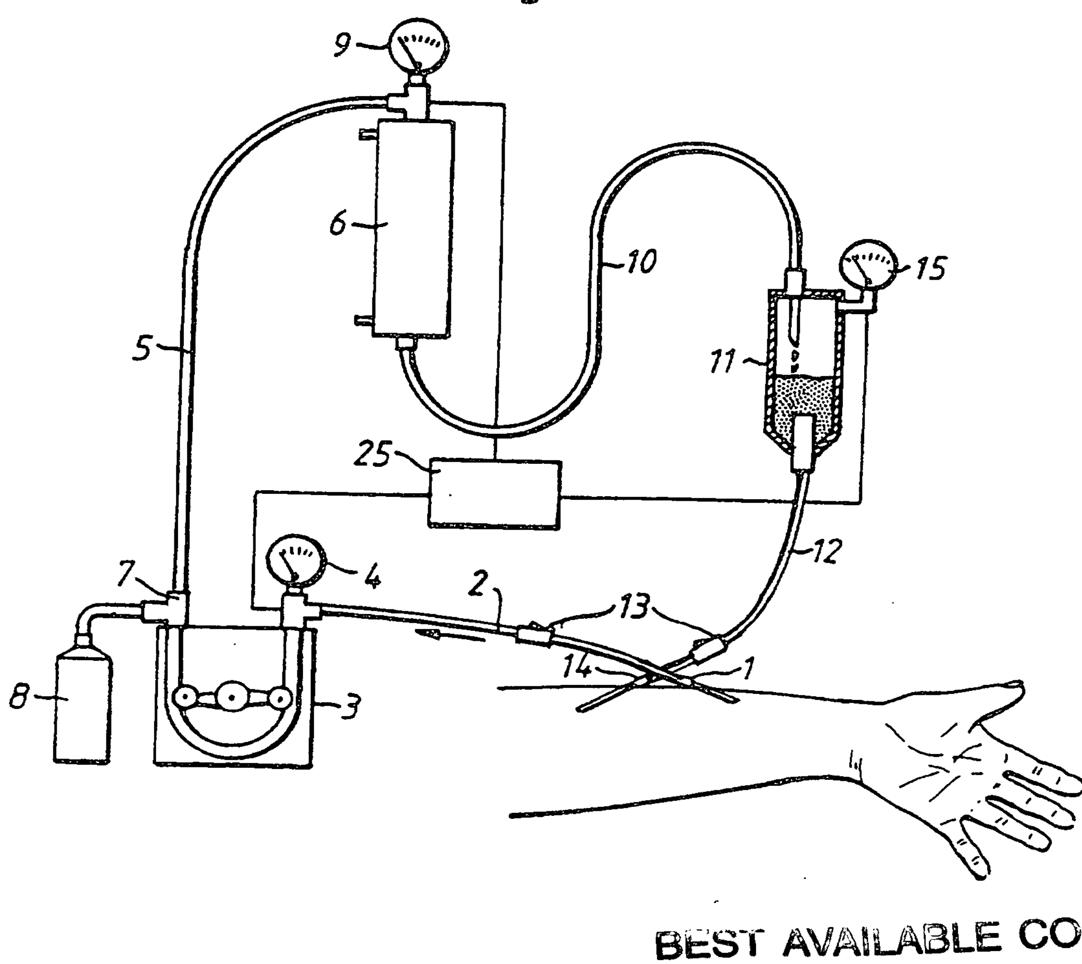


Fig.3

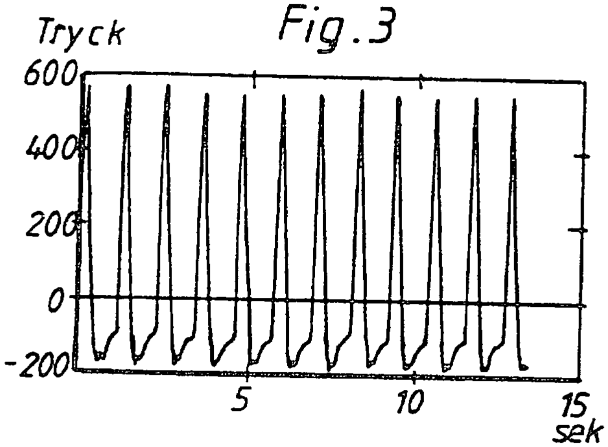


Fig.4

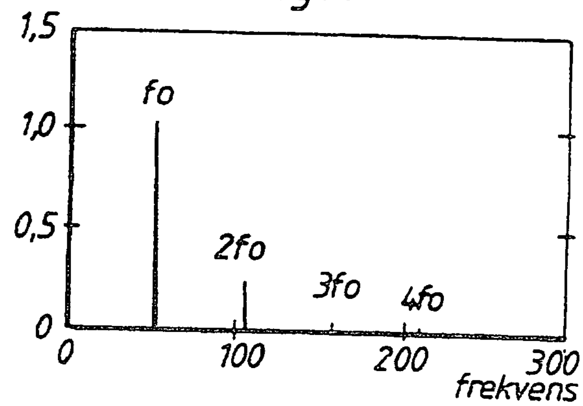


Fig.5

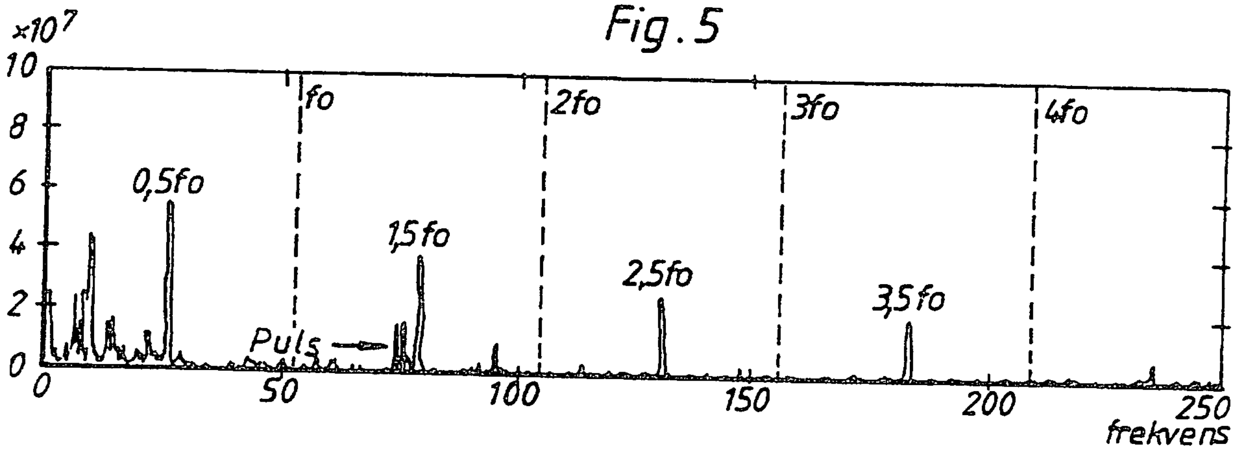


Fig.6

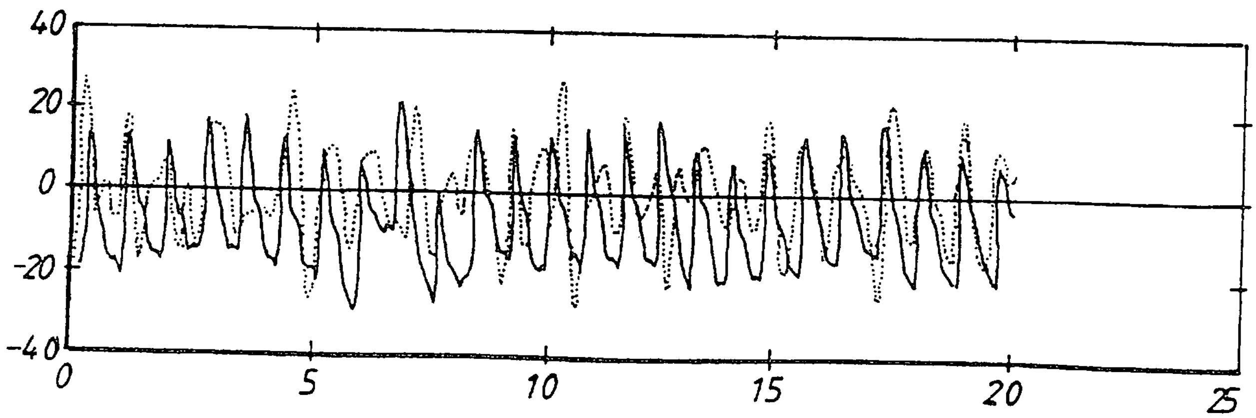


Fig.7